CLINICAL STUDIES AND TRIALS UNIT
DIVISION OF DEVELOPMENT RESEARH
INDIAN COUNCIL OF MEDICAL RESEARCH

'Expression of Interest' to select candidates for regulation compliant clinical development of Therapeutics/Vaccines

Background

ICMR-DHR, as the apex biomedical research body in India, supports the development of regulation compliant innovative therapeutics & vaccines of National Health Priority through various research initiatives such as MedTech Mitra and INTENT (Indian Clinical Trial and Education Network). It has been seen that many innovators, especially Academics, Start-ups and individual innovators are ready with their proof of concepts and prototypes but require specific support in regulation-compliant clinical evaluation, in the form of Phase I/II/III clinical trials of their healthcare products.

Purpose

ICMR plans to extend guidance and support for clinical evaluation of promising products addressing health conditions of national priority. For the purpose of this EoI, the candidates for drugs, biologics and vaccines will be hereafter denoted as healthcare products. Researchers working in India having promising lead candidates (with requisite data for regulatory approvals) that are ready to be taken up for various phases of clinical development, are encouraged to submit their expressions of interest. Innovations in existing products (improved formulation, new route of administration, new indication, etc.) with cogent rationale and preclinical proof of concept or evidence of therapeutic advantage may also be considered.

Scope

Applicant should preferably be the inventor (Academia, Start-up, Industry), having a candidate product with demonstrated preclinical efficacy and toxicity studies as per Indian regulatory requirements. Site for phase I clinical trials will be identified from the ICMR Phase I clinical trial network and for phase II/III studies will be identified from ICMR – INTENT network.

Applicants should be:

-Ready with or applied for a Test Batch License:

-Ready with or ready for submission of the Investigational New Drug dossier/SND for the approval to conduct human safety and efficacy studies (Phase I/II/III clinical trials)

Candidates with insufficient data to support its preclinical efficacy will be excluded. Candidates for diagnostics and medical devices will be excluded.

Submission of EoIs:
All EoIs are to be submitted via ICMR-ePMS in the format provided in annexure I.

Steps for submitting EoI online via ePMS portal:

1. **Login** to ICMR ePMS portal (**https://epms.icmr.org.in/userLogin**) -> Fill in the Personal Details.
2. Click on '**Proposal Submission**' under Profile Panel -> **EOI** -> Click on '**Add new EoI proposal**' in top left **blue** box -> Fill in the EoI form step-by-step.

Review of EoIs
All EoIs will be reviewed in accordance with the timelines given below (see "Timelines" section). EoIs received after July 31, 2025 will be reviewed in subsequent review cycles to be schedule periodically.

The review will be carried out by an independent selection committee constituted by ICMR based on the following criteria and the data/ evidence submitted in support of the same:

1. Novelty – whether the candidate is innovative
2. Need for the product – comparative advantage over existing standard of care
3. National priority - likely impact on disease burden
4. Techno-commercial evaluation – whether the candidate will have a reasonable marketable Relevance.
5. Readiness for regulatory approval from the Central Licensing Authority, India

Approval from the competent authority of ICMR will be final.

Expected outcomes

1) Clinical co-development of healthcare products that meet national health priorities
2) Accelerated development of Evidence-based healthcare ecosystem in the country

Timelines:

Release of Call: 01 July 2025
Last date of submission of proposal: 31 July 2025
Review and selection: Mid-September 2025
Proposal refinement& final submission of documents: Mid-October 2025
Approval: Mid-November 2025

For any technical queries related to the call, please contact: po.epms@icmr.gov.in
For any scientific queries related to the call, please contact: Sudipto.roy@icmr.gov.in

Annexure I - Format for EoI

1) **Details of investigator/** inventor (including name, designation and affiliation of researcher(s) working in India)
2) Contact details – phone & email
3) Summary of product (in less than 250 words)
4) Type of candidate: Drug/ biological/ vaccine/other
    a. Please describe if any other
    b. Is it a health product from alternate systems of medicine - Y/ N?
    c. Is it a diagnostic - Y/ N?
5) Proposed indication(s) –not more than 3
6) Is the lead novel candidate suitable for a clinical trial – Y/ N/ Don't know
7) If Yes, is it suitable for a Phase I /II/III trial?
8) For Phase-I, Is GLP preclinical efficacy data available as per regulatory standards– Y/N/ Partially/ Don't know
    a. If available, give details (should not exceed 250 words pages)
    b. Details (as per D&C Act) – Hyperlink to one single PDF submission page
9) For Phase-I, Is GLP toxicity data available as per regulatory standards– Y/N/ Partially/ Don't know
    a. If available, give details (should not exceed 250 words pages)
    b. Details (as per D&C Act) – Hyperlink to one single PDF submission page
10) For Phase-II/III, Is Phase I data available as per regulatory standards– Y/N/ Partially/ Don't know
    a. If available, give details (should not exceed 250 words pages)
    b. Details (as per D&C Act) – Hyperlink to one single PDF submission page
11) Inputs on each of the review criteria (upto 500 words each). Documentary evidence to be uploaded for each.
    a. Need for the product
    b. Novelty
    c. Impact on the health condition
    d. Techno-commercial evaluation
    e. Readiness for regulatory approval

12) In case of EoI from academia/ NGO, please share details of potential technology transfer agreements being planned (in less than 100 words)
13) Describe the future plans for possible product development lifecycle/ clinical development plans (in less than 250 words)
14) Have you identified a GMP manufacturing facility GMP – Y/ N
    a. If available, provide a brief summary (in less than 100 words)
15) Study design/ regulatory expertise available – Y/ N
    a. If available, please mention the details of the team and strengths
16) Valid DSIR certificate available – Y/ N
17) Current & immediate intellectual property status (upto 250 words).